



UNITED STATES ENVIRONMENTAL PROTECTION AGENCY
REGION 5
77 WEST JACKSON BOULEVARD
CHICAGO, IL 60604-3590

JUN 28 2018

REPLY TO THE ATTENTION OF:

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Michael Shuler
Environmental Specialist
MilliporeSigma
4353 East 49th Street
Cleveland, Ohio 44125

Re: Finding of Violation
MilliporeSigma
Cleveland, Ohio

Dear Michael Shuler:

The U.S. Environmental Protection Agency is issuing the enclosed Finding of Violation (FOV) to MilliporeSigma (you) under Section 113(a)(3) of the Clean Air Act, 42 U.S.C. § 7413(a)(3). We find that you are violating the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Miscellaneous Organic Chemical Manufacturing at 40 C.F.R. Part 63, Subpart FFFF; the NESHAP for Organic Hazardous Air Pollutants From the Synthetic Organic Chemical Manufacturing Industry for Process Vents, Storage Vessels, Transfer Operations, and Wastewater at the 40 C.F.R. Part 63, Subpart G; the NESHAP for Closed Vent Systems, Control Devices, Recovery Devices and Routing to a Fuel Gas System or a Process, at 40 C.F.R. Part 63, Subpart SS; and the NESHAP for Equipment Leaks—Control Level 2 Standards at 40 C.F.R. Part 63, Subpart UU; at your Cleveland, Ohio facility.

Section 113 of the Clean Air Act gives us several enforcement options. These options include issuing an administrative compliance order, issuing an administrative penalty order and bringing a judicial civil or criminal action.

We are offering you an opportunity to confer with us about the violations alleged in the FOV. The conference will give you an opportunity to present information on the specific findings of violation, any efforts you have taken to comply and the steps you will take to prevent future violations. In addition, in order to make the conference more productive, we encourage you to submit to us information responsive to the FOV prior to the conference date.

Please plan for your facility's technical and management personnel to attend the conference to discuss compliance measures and commitments. You may have an attorney represent you at this conference.

The EPA contacts in this matter are Luke Hullinger and Albana Bega. You may call them at (312) 886-3011 and (312) 353-4789 to request a conference. You should make the request within 10 calendar days following receipt of this letter. We should hold any conference within 30 calendar days following receipt of this letter.

Sincerely,



Edward Nam
Director
Air and Radiation Division

cc: Bob Hodanbosi, Chief, Division of Air Pollution Control

IN THE MATTER OF:

FINDING OF VIOLATION

EPA-5-18-OH-08

The U.S. Environmental Protection Agency finds that MilliporeSigma (a business of Merck KGaA and owned by or affiliated with Sigma-Aldrich Corp.) (hereinafter MilliporeSigma) is violating Section 112 of the Clean Air Act (CAA), 42 U.S.C. § 7412 at its Cleveland, Ohio facility. (Other names associated with this facility include Research Organics LLC and SAFC Cleveland). Specifically, MilliporeSigma is violating the National Emission Standards for Hazardous Air Pollutants (NESHAP) for Miscellaneous Organic Chemical Manufacturing at 40 C.F.R. Part 63, Subpart FFFF, the NESHAP for Organic Hazardous Air Pollutants From the Synthetic Organic Chemical Manufacturing Industry for Process Vents, Storage Vessels, Transfer Operations, and Wastewater at the 40 C.F.R. Part 63, Subpart G, the NESHAP for Closed Vent Systems, Control Devices, Recovery Devices and Routing to a Fuel Gas System or a Process, at 40 C.F.R. Part 63, Subpart SS, and the NESHAP for Equipment Leaks—Control Level 2 Standards, at 40 C.F.R. Part 63, Subpart UU as follows:

NESHAP

1. Pursuant to Section 112(b) of the CAA, 42 U.S.C. § 7412(b), EPA designates hazardous air pollutants (HAPs) which present or may present a threat of adverse effects to human health or the environment.
2. Section 112(a) of the CAA, 42 U.S.C. § 7412(b), defines "major source" as any stationary source or group of stationary sources located within a contiguous area and under common control that emits or has the potential to emit considering controls, in the aggregate, 10 tons per year (tpy) or more of any HAP or 25 tpy or more of any combination of HAPs.
3. Section 112(c) and (d) of the CAA, 42 U.S.C. § 7412(c), requires EPA to publish a list of categories of sources that EPA finds present a threat of adverse effects to human health or the environment due to emissions of HAPs, and to promulgate emission standards for each source category. These standards are known as "national emission standards for hazardous air pollutants" or "NESHAP." EPA codifies these requirements at 40 C.F.R. Parts 61 and 63.

4. The NESHAP in 40 C.F.R. Part 63 are national technology-based performance standards for HAP sources in each category that become effective on a specified date. The purpose of these standards is to ensure that all sources achieve the maximum degree of reduction in emissions of HAPs that EPA determines is achievable for each source category.

5. Section 112(i)(3) of the CAA, 42 U.S.C. § 7412(i)(3), prohibits any person subject to a NESHAP from operating an existing source in violation of a NESHAP after its effective date. *See* 40 C.F.R. § 63.4.

6. The NESHAP, at 40 C.F.R. Part 63, Subpart A, contains general provisions applicable to the owner or operator of any stationary source that contains an affected source subject to a relevant standard in 40 C.F.R. Part 63, to the extent specified in such standard.

7. The NESHAP, at 40 C.F.R. § 63.2, Subpart A, defines “affected source” as the collection of equipment, activities, or both within a single contiguous area and under common control that is included in a CAA Section 112(c) source category or subcategory for which a Section 112(d) standard or other relevant standard is established pursuant to Section 112 of the CAA.

8. The NESHAP, at 40 C.F.R. § 63.2, defines “existing source” as any affected source that is not a new source.

9. The NESHAP, at 40 C.F.R. § 63.2, defines “new source” as any affected source the construction or reconstruction of which is commenced after EPA first proposes a relevant emission standard under 40 C.F.R. Part 63 establishing an emission standard applicable to such source.

NESHAP for Miscellaneous Organic Chemicals Manufacturing (MON or Subpart FFFF)

10. On November 10, 2003, EPA promulgated Subpart FFFF, 68 Fed. Reg. 63888 (November 10, 2003). The owner or operator of an existing affected source as of November 10, 2003, was required to come into compliance with the provisions of Subpart FFFF no later than three years later or by November 10, 2006, which was subsequently revised to require compliance by no later than May 10, 2008, as currently provided by 40 C.F.R. § 63.2445(b).

11. Subpart FFFF, at 40 C.F.R. § 63.2435(a), applies to owners or operators of miscellaneous organic chemicals manufacturing process units (MCPUs) that are located at, or are part of, a major source of HAP emissions, as defined in Section 112(a) of the CAA, 42 U.S.C. § 7412(a).

12. Subpart FFFF, at 40 C.F.R. § 63.2550, defines “miscellaneous organic chemical manufacturing process” as all equipment which collectively functions to produce a product or isolated intermediate that is “material” described in 40 C.F.R. § 63.2435(b). “Process” includes any, all or a combination of reaction, recovery, separation, purification, or other activity, operation, manufacture, or treatment which are used to produce a product or isolated intermediate.

13. Subpart FFFF, at 40 C.F.R. § 63.2435(b), states that an MCPU includes equipment necessary to operate a miscellaneous organic chemical manufacturing process, as defined in 40 C.F.R. § 63.2550, that satisfies all of the conditions specified in paragraphs (b)(1) through (3) of 40 C.F.R. § 63.2435. An MCPU also includes any assigned storage tanks and transfer racks; equipment in open systems that is used to convey or store water having the same concentration and flow characteristics as wastewater; and components such as pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, and instrumentation systems that are used to manufacture any material or family of materials described in paragraphs (b)(1)(i) through (v) of 40 C.F.R. § 63.2435.

14. Subpart FFFF, at 40 C.F.R. § 63.2540, provides that owners or operators of MCPUs must also comply with the requirements of Subpart A, as identified in Table 12 of Subpart FFFF.

15. Subpart FFFF, at 40 C.F.R. § 63.2450 (a), states in pertinent part that owners and operators of MCPUs must be in compliance with the emission limits and work practice standards in Tables 1 through 7 as specified therein, must meet the applicable requirements specified in 40 C.F.R. §§ 63.2455 through 2490 as specified therein, and must meet the notification, reporting, and recordkeeping requirements specified in 40 C.F.R. §§ 63.2515, 63.2520, and 63.2525. References herein to Tables refer to tables included in 40 C.F.R. Part 63, Subpart FFFF.

16. Subpart FFFF, at 40 C.F.R. § 63.2450(c), with requirements for combined emission streams, states that when organic HAP emissions from difference emission types (e.g., continuous process vents, batch process vents, storage tanks, transfer operations, and waste management units) are combined, then the owner or operator of MCPUs must comply with the requirements in 40 C.F.R. §63.2450(c)(1) or 63.2450(c)(2).

17. Subpart FFFF, at 40 C.F.R. § 63.2450(e)(1), requires that (except when complying with 40 C.F.R. § 63.2485 for wastewater streams), if the owner or operator of MCPUs is reducing the organic HAP emissions by venting emissions through a closed-vent system to any combination of control devices (except a flare) or recovery devices, the owner or operator must meet the requirements of Subpart SS at 40 C.F.R. § 63.982(c) and the requirements referenced therein.

18. Subpart FFFF, at 40 C.F.R. § 63.2450(e)(3), requires that if the owner or operator of MCPUs is using a halogen reduction device to reduce hydrogen halide and halogen HAP emissions from halogenated vent streams, the owner or operator must meet the requirements of 40 C.F.R. § 63.994 and the requirements referenced therein.

A. Requirements for Batch Process Vents (40 C.F.R. § 63.2460) and for Process Vents that Emit Hydrogen Halide and Halogen HAP (40 C.F.R. § 63.2465)

19. Subpart FFFF, at 40 C.F.R. § 63.2460(a), with requirements for batch process vents, states in pertinent part that owners or operators of MCPUs must meet each applicable emission limit in Table 2, and each applicable requirement specified in paragraphs (b) and (c) of 40 C.F.R. § 63.2460.

20. Table 2 of Subpart FFFF requires owners or operators of MCPUs that are subject to 40 C.F.R. § 2460 to reduce collective uncontrolled organic HAP emissions from the sum of all Group 1 batch process vents within each process with Group 1 batch process units by ≥ 98 percent (%) by weight by venting emissions from a sufficient number of the vents through one or more closed-vent systems to any combination of control devices (except a flare).

21. Table 2 of Subpart FFFF requires owners or operators of MCPUs that are subject to 40 C.F.R. § 2460 to use either: (i) a halogen reduction device after the combustion control device, and to reduce overall emissions of hydrogen halide and halogen HAP by $\geq 99\%$, or to ≤ 0.45 kilograms per hour, or to a concentration ≤ 20 part per million by volume, for halogenated Group 1 batch process vents for which the owner or operator uses a combustion device to control organic HAP emissions; or (ii) a halogen reduction device before the combustion control device to reduce the halogen atom mass emission rate to ≤ 0.45 kg/hr or to a concentration ≤ 20 ppmv.

22. Subpart SS, at 40 C.F.R. § 63.982(c), states in pertinent part that owners or operators of MCPUs who control emissions from process vents through a closed vent system to a nonflare control device shall meet numerous requirements, including but not limited to: (i) the requirements for closed vent systems in 40 C.F.R. § 63.983; (ii) with respect to the control device being used, the requirements in 40 C.F.R. §§ 63.988 (applicable to incinerators used as the control device) pertaining to the operation of the control device, performance test requirements for the control device and a requirement to use a continuous parameter monitoring system (CPMS) for recording temperature; (iii) the requirements in 40 C.F.R. § 63.996 including operating requirements, requirements for a performance test, and requirements to establish an operating limit for temperature that indicates proper operation of the control device and to report that operating limit in the Notice of Compliance Status or the operating permit application; (iv) the applicable performance test requirements in 40 C.F.R. § 63.997; and (v) the requirements of 40 C.F.R. § 63.998 including requirements for keeping continuous CPMS records; and (vi) the requirements in 40 C.F.R. § 63.999 requiring notifications and reports, including the requirement that the NOCS include a description of the parameter or parameters to be monitored to ensure that the control device is being properly operated and maintained and the requirement that the Periodic Reports (Compliance Reports) must report operating deviations from monitored parameters.

23. Subpart FFFF, at 40 C.F.R. § 63.2460(c), includes exceptions to certain requirements in Subpart SS for batch process vents.

24. Subpart FFFF, at 40 C.F.R. § 63.2465(a), with requirements for process vents that emit hydrogen halide and halogen HAP, states in pertinent part that owners or operators of MCPUs must meet each emission limit in Table 3 and each applicable requirement in paragraphs (b) through (d) of 40 C.F.R. § 63.2465(a).

25. Table 3 of Subpart FFFF requires owners or operators of MCPUs at an existing source that are subject to 40 C.F.R. § 63.2465 to either: (i) reduce collective hydrogen halide and halogen HAP emissions by ≥ 99 percent by weight or to an outlet concentration ≤ 20 ppmv by venting through one or more closed-vent systems to any combination of control devices; or (ii) reduce the halogen atom mass emission rate from the sum of all batch process vents and each

individual continuous process vent to ≤ 0.45 kg/hr by venting through one or more closed-vent systems to a halogen reduction device.

26. Subpart FFFF, at 40 C.F.R. § 63.2465(c), states that if collective uncontrolled hydrogen halide and halogen HAP emissions from the process vents within a process are greater than or equal to 1,000 pounds per year (lb/yr), owners or operators must comply with Subpart SS at 40 C.F.R. § 63.994 and the requirements referenced therein, except as specified in paragraphs (c)(1) through (3) of 40 C.F.R. § 63.2465(c).

27. Subpart SS, at 40 C.F.R. § 63.994(b)(1), as modified by 40 C.F.R. § 63.2465(c)(1), states in pertinent part that where a halogen scrubber or other halogen reduction device is used to control halogenated vent streams in accordance with Subpart FFFF (among other subparts), the owner or operator shall conduct an initial performance test (or a design evaluation in accordance with 40 C.F.R. § 63.1257(a)(1)) to determine compliance with the control efficiency or emission limits for hydrogen halides and halogens according to the procedures in 40 C.F.R. § 63.997. Subpart SS, at 40 C.F.R. § 63.994(c) requires a pH monitoring device and flow meter capable of providing a continuous record. Subpart SS, at 40 C.F.R. § 63.994(c) also requires compliance: (i) with the requirements in 40 C.F.R. § 63.996 including operating requirements, requirements for the performance test, and requirements to establish monitored parameters that indicate proper operation of the scrubber and to report those operating parameters in the Notice of Compliance Status or the operating permit application; and (ii) with the requirements in 40 C.F.R. § 63.998(b) and (c), requiring continuous records of monitored parameters, and reporting deviations in the periodic reports (compliance reports).

28. Subpart SS, at 40 C.F.R. § 63.2550, defines “deviation” as “any instance in which an affected source subject to this subpart, or an owner or operator of such a source: (1) Fails to meet any requirement or obligation established by this subpart including, but not limited to, any emission limit, operating limit, or work practice standard; or (2) Fails to meet any term or condition that is adopted to implement an applicable requirement in this subpart and that is included in the operating permit for any affected source required to obtain such a permit; or (3) Fails to meet any emission limit, operating limit, or work practice standard in this subpart during startup, shutdown, or malfunction, regardless of whether or not such failure is permitted by this subpart.”

29. Subpart FFFF, at 40 C.F.R. § 63.2465(c)(1), states that owners or operators may elect to conduct a design evaluation in accordance with 40 C.F.R. § 63.1257(a)(1), when Subpart SS at 40 C.F.R. § 63.994(b)(1) requires a performance test.

B. Requirements for Equipment Leaks

30. Subpart FFFF, at 40 C.F.R. § 63.2480(a) with requirements for equipment leaks, states that owners or operators of MCPUs must meet each requirement in Table 6 that applies to the owner or operator’s equipment leaks, except as specified in paragraph (b) through (d) of 40 C.F.R. § 63.2480.

31. Table 6 of Subpart FFFF requires that all equipment in organic HAP service must comply with the requirements of either 40 C.F.R. Part 63, Subpart UU, or Subpart H, and the

requirements referenced therein, except as specified in 40 C.F.R. § 63.2480(b) and (d), or 40 C.F.R. Part 65, Subpart F, and the requirements referenced therein, except as specified in 40 C.F.R. § 63.2480(c) and (d).

32. Subpart FFFF, at 40 C.F.R. § 63.2550, defines “in organic HAP service” with respect to a piece of equipment as a piece of equipment that either contains or contacts a fluid (liquid or gas) that is at least 5% by weight of total organic HAP as determined according to the provisions of 40 C.F.R. Part 63, Subpart H, at 40 C.F.R. § 63.180(d).

C. Requirements for Wastewater Streams

33. Subpart FFFF, at 40 C.F.R. § 63.2485(a), with requirements for wastewater streams, states in pertinent part that owners or operators of MCPUs must meet each requirement in Table 7 that applies to the owner or operator’s wastewater streams, except as specified in paragraphs (b) through (o) of the 40 C.F.R. § 63.2485.

34. Table 7 of Subpart FFFF requires that each process wastewater stream must comply with the requirements in 40 C.F.R. §§ 63.132 through 63.148 of Subpart G, and the requirements referenced therein, except as specified in the 40 C.F.R. § 63.2485.

35. Subpart FFFF, at 40 C.F.R. § 63.2550, defines “wastewater” as the water that is discarded from an MCPU or control device through a POD and that contains either: an annual average concentration of compounds in Tables 8 and 9 to this subpart of at least 5 parts per million by water (ppmw) and has an annual average flowrate of 0.02 liters per minute or greater; or an annual average concentration of compounds in Tables 8 and 9 to this subpart of at least 10,000 ppmw at any flowrate. Wastewater means process wastewater or maintenance wastewater.

36. Subpart FFFF, at 40 C.F.R. § 63.2550, defines “point of determination (POD)” as each point where process wastewater exits the MCPU or control device.

37. Subpart FFFF, at 40 C.F.R. § 63.2550, defines “Group 1 wastewater stream” as a wastewater stream consisting of process wastewater at an existing or new source that meets the criteria for Group 1 status in 40 C.F.R. § 63.2485(c) for compounds in Tables 8 and 9 to this subpart and/or a wastewater stream consisting of process wastewater at a new source that meets the criteria for Group 1 status in 40 C.F.R. § 63.132(d) for compounds in Table 8 to Subpart G of Part 63.

38. Subpart FFFF, at 40 C.F.R. § 63.2550, defines “Group 2 wastewater stream” as any process wastewater stream that does not meet the definition of a Group 1 wastewater stream.

The NESHAP General Provisions (Subpart A)

39. The General Provisions for the NESHAP are codified at 40 C.F.R. Part 63, Subpart A.

40. Subpart A, at 40 C.F.R. § 63.6(c)(5) states “the owner or operator of an area source that increases its emissions of (or its potential to emit) HAPs such that the source

becomes a major source shall be subject to relevant standards for existing sources. Such sources must comply by the date specified in the standards for existing area sources that become major sources. If no such compliance date is specified in the standards, the source shall have a period of time to comply with the relevant emission standard that is equivalent to the compliance period specified in the relevant standard for existing sources in existence at the time the standard becomes effective.”

41. Subpart A, at 40 C.F.R. § 63.6(e)(1) states “[a]t all times, including periods of startup, shutdown, and malfunction, the owner or operator must operate and maintain any affected source, including associated air pollution control equipment and monitoring equipment, in a manner consistent with safety and good air pollution control practices for minimizing emissions.”

42. Subpart A, at 40 C.F.R. § 63.10(b)(2)(vii) requires that the owner or operator of an affected source maintain relevant records of required measurements needed to demonstrate compliance with a relevant standard (including, but not limited to, 15-minute averages of continuous monitoring system data).

NESHAP for the Synthetic Organic Chemical Manufacturing Industry for Process Vents, Storage Vessels, Transfer Operations, and Wastewater (Subpart G)

43. On April 22, 1994, EPA promulgated the NESHAP for the Synthetic Organic Chemical Manufacturing Industry for Process Vents, Storage Vessels, Transfer Operations and Wastewater (Subpart G), 59 Fed. Reg. 19468 (April 22, 1994).

44. As stated in paragraphs 33 and 34, among the requirements of Subpart FFFF is 40 C.F.R. § 63.2485(a) and Table 7, which require that organic manufacturing facilities comply with the requirements in 40 C.F.R. §§ 63.132 through 63.148 of Subpart G, for each process wastewater stream.

45. Subpart G, at 40 C.F.R. § 63.111, defines a “wastewater stream” as “...a stream that contains only wastewater as defined in 40 C.F.R. §63.101 of Subpart F of this part.”

46. Subpart G, at 40 C.F.R. § 63.132(g), states that owners or operators “may elect to transfer a Group 1 wastewater stream or residual removed from a Group 1 wastewater stream to an on-site treatment operation not owned or operated by the owner or operator of the source generating the wastewater stream or residual, or to an off-site treatment operation.”

47. Subpart G, at 40 C.F.R. § 63.132(g)(1)(i), states that owners or operators transferring the wastewater stream or residual shall comply with the provisions specified in 40 C.F.R. §§ 63.133 through 63.137 of Subpart G for each waste management unit that receives or manages a Group 1 wastewater stream or residual removed from a Group 1 wastewater stream prior to shipment or transport.

48. Subpart G, at 40 C.F.R. § 63.111, defines a “waste management unit” as the equipment, structure(s), and/or device(s) used to convey, store, treat, or dispose of wastewater streams or residuals. Examples of waste management units include: wastewater

tanks, surface impoundments, individual drain systems, and biological wastewater treatment units.

49. Subpart G, at 40 C.F.R. § 63.133(a), states that for each wastewater tank that receives, manages, or treats a Group 1 wastewater stream or a residual removed from a Group 1 wastewater stream, the owner or operator shall comply with the requirements of either paragraph (a)(1) or (a)(2) of this section as specified in Table 10 of Subpart G.

50. Table 10 of Subpart G requires that each wastewater tank of capacity of less than 75 cubic meters must comply with requirements in 40 C.F.R. § 63.133(a)(1) of Subpart G.

51. Subpart G, at 40 C.F.R. § 63.133(a)(1), requires owners or operators to operate and maintain a fixed roof for each wastewater tank that receives, manages, or treats a Group 1 wastewater stream or a residual removed from a Group 1 wastewater stream, except that if the wastewater tank is used for heating wastewater, or treating by means of an exothermic reaction or the contents of the tank is sparged, the owner or operator shall comply with the requirements specified in paragraph (a)(2) of this section.

52. Subpart G, at 40 C.F.R. § 63.139(a), requires owners or operators to maintain and operate the control device or combination of control devices used to comply with the provisions in 40 C.F.R. §§ 63.133 through 63.138 of Subpart G, in accordance with the requirements of paragraphs (b) through (f) of 40 C.F.R. § 63.139.

53. Subpart G, at 40 C.F.R. § 63.139(b), states that whenever HAP emissions are vented to a control device which is used to comply with the provisions of this subpart, such control device shall be operating.

54. Subpart G, at 40 C.F.R. § 63.139(c)(1), requires enclosed combustion devices to meet the conditions in paragraph (c)(1)(i), (c)(1)(ii), or (c)(1)(iii) of 40 C.F.R. § 63.139(c)(1).

55. Subpart G, at 40 C.F.R. § 63.139(d), requires owners or operators to demonstrate that each control device or combination of control devices achieves the appropriate conditions specified in 40 C.F.R. § 63.139(c) by using one or more of the methods specified in paragraphs (d)(1), (d)(2), or (d)(3) of 40 C.F.R. § 63.139(d), except as provided in paragraph (d)(4) of 40 C.F.R. § 63.139(d).

56. Subpart G, at 40 C.F.R. § 63.139(d)(2)(vii), states that “[f]or a scrubber, the design evaluation shall consider the vent stream composition; constituent concentrations; liquid-to-vapor ratio; scrubbing liquid flow rate and concentration; temperature; and the reaction kinetics of the constituents with the scrubbing liquid. The design evaluation shall establish the design exhaust vent stream organic compound concentration level and will include the additional information in paragraphs (d)(2)(vii)(A) and (d)(2)(vii)(B) of this section for trays and a packed column scrubber.”

NESHAP for Equipment Leaks – Control Level 2 (Subpart UU)

57. On June 29, 1999, EPA promulgated the 40 C.F.R. Part 63, Subpart UU, 64 Fed. Reg. 34899 (June 29, 1999).

58. Subpart UU, at 40 C.F.R. § 63.1019(b), states that "[t]he provisions of this subpart and the referencing subpart apply to equipment that contains or contacts regulated material. This subpart applies to pumps, compressors, agitators, pressure relief devices, sampling connection systems, open-ended valves or lines, valves, connectors, instrumentation systems, and closed vent systems and control devices used to meet the requirements of this subpart."

59. Subpart UU, at 40 C.F.R. § 63.1020, defines "closed-vent system" as a system that is not open to the atmosphere and is composed of piping, ductwork, connections, and, if necessary, flow inducing devices that transport gas or vapor from an emission point to a control device.

60. Subpart UU, at 40 C.F.R. § 63.1020, defines "connector" as flanged, screwed, or other joined fittings used to connect two pipelines or a pipeline and a piece of equipment. A common connector is a flange. Joined fittings welded completely around the circumference of the interface are not considered connectors for the purpose of this regulation. For the purpose of reporting and recordkeeping, connector means joined fittings that are not inaccessible, ceramic, or ceramic-lined (e.g., porcelain, glass, or glass-lined) as described in 40 C.F.R. § 63.1027(e)(2).

61. Subpart UU, at 40 C.F.R. § 63.1022(a), states that "equipment subject to this subpart shall be identified. Identification of the equipment does not require physical tagging of the equipment. For example, the equipment may be identified on a plant site plan, in log entries, by designation of process unit or affected facility boundaries by some form of weatherproof identification, or by other appropriate methods."

62. Subpart UU, at 40 C.F.R. § 63.1025(b)(1), requires that valves shall be monitored to detect leaks by the method specified in 40 C.F.R. § 63.1023(b) and, as applicable, 40 C.F.R. § 63.1023(c).

63. Subpart UU, at 40 C.F.R. § 63.1025(b)(3)(i) states that "[i]f at least the greater of 2 valves or 2 % of the valves in a process unit leak, as calculated according to paragraph (c) of this section, the owner or operator shall monitor each valve once per month."

64. Subpart UU, at 40 C.F.R. § 63.1023(b)(1), requires that instrument monitoring shall comply with Method 21 of 40 C.F.R. Part 60, Appendix A.

65. Subpart UU, at 40 C.F.R. § 63.1027(b), states that the owner or operator shall monitor all connectors in gas and vapor and light liquid service as specified in paragraphs (a) and (b)(3) of this section, except as allowed in 40 C.F.R. § 63.1021(b), 40 C.F.R. § 63.1036, 40 C.F.R. § 63.1037, or as specified in paragraph (e) of 40 C.F.R. § 63.1027.

66. Subpart UU, at 40 C.F.R. § 63.1034(b)(2) requires owners or operators of closed vent systems and control devices used to comply with the provisions of this subpart to comply with the provisions of Subpart SS of this part and (b)(2)(i) through (b)(2)(iii) of this section.

67. Subpart UU, at 40 C.F.R. § 63.1034(b)(2)(ii) requires enclosed combustion devices to be designed and operated to reduce emissions of regulated material vented to them with an efficiency of 95 % or greater, or to an exit concentration of 20 ppmv, on a dry basis,

corrected to 3 % oxygen, whichever is less stringent, or to provide a minimum residence time of 0.50 seconds at a minimum temperature of 760 °C (1400 °F).

NESHAP for Closed Vent Systems, Control Devices, Recovery Devices and Routing to a Fuel Gas System or a Process (Subpart SS)

68. On June 29, 1999, EPA promulgated the 40 C.F.R. Part 63, Subpart SS, 64 Fed. Reg. 34866 (June 29, 1999).

69. Subpart SS, at 40 C.F.R. § 63.982(c), states that owners or operators who control emissions through a closed vent system to a nonflare control device shall meet the requirements in 40 C.F.R. § 63.983 for closed vent systems, the applicable recordkeeping and reporting requirements of 40 C.F.R. §§ 63.998 and 63.999, and the applicable requirements listed in paragraphs (c)(1) through (3) of 40 C.F.R. § 63.982.

70. Subpart SS, at 40 C.F.R. § 63.983(a), applies to closed vent systems collecting regulated material from a regulated source that are not maintained under negative pressure.

71. Subpart SS, at 40 C.F.R. § 63.983(a)(1), states that “[e]ach closed vent system shall be designed and operated to collect the regulated material vapors from the emission point, and to route the collected vapors to a control device.”

72. Subpart SS, at 40 C.F.R. § 63.983(a)(2), requires that closed vent systems used to comply with the provisions of Subpart SS shall be operated at all times when emissions are vented to, or collected by, them.

73. Subpart SS, at 40 C.F.R. § 63.983(c)(1)(i), requires owners or operators of closed vent systems collecting regulated material from a regulated source to conduct inspections in accordance with Method 21 of 40 CFR Part 60, appendix A.

74. Subpart SS, at 40 C.F.R. § 63.994(a)(1), states that “an owner or operator of a halogen scrubber or other halogen reduction device subject to this subpart shall reduce the overall emissions of hydrogen halides and halogens by the control device performance level specified in a referencing subpart.”

75. Subpart SS, at 40 C.F.R. § 63.994(a)(2), states that “halogen scrubbers and other halogen reduction devices used to comply with the provisions of a referencing subpart and this subpart shall be operated at all times when emissions are vented to them.”

76. Subpart SS, at 40 C.F.R. § 63.994(c)(1), requires owners or operators of a halogen scrubber to use monitoring equipment specified in paragraphs (c)(1)(i) and (ii) of this section, and to record monitoring results as specified in 40 C.F.R. § 63.998(b) and (c).

77. Subpart SS, at 40 C.F.R. § 63.994(c)(1)(i), requires owners or operators of a halogen scrubber to install a pH monitoring device to continuously monitor and record the pH of the scrubber effluent.

78. Subpart SS, at 40 C.F.R. § 63.994(c)(1)(ii), requires owners or operators of a halogen scrubber to install a flow meter at the scrubber influent to provide a continuous record for liquid flow. Subpart SS, at 40 C.F.R. § 63.998(b)(1), requires owners or operators to maintain a record as specified in paragraphs (b)(1)(i) through (iv) of 40 C.F.R. § 63.998(b)(1), where a continuous record is required by Subpart SS.

Title V Requirements

79. Section 502(a) of the CAA, 42 U.S.C. § 7661a(a), provides that it is unlawful to violate any requirement of a permit promulgated under Title V of the CAA. EPA first promulgated regulations governing state operating permit programs on July 21, 1992. See 57 Fed. Reg. 32295; 40 C.F.R. Part 70.

80. 40 C.F.R. § 70.6(b)(1) provides that Title V permits are federally enforceable and that all terms and conditions in a Title V permit, including any provisions designed to limit a source's potential to emit, are enforceable by EPA.

81. 40 C.F.R. § 70.2 defines "major source," in part, as any stationary source belonging to a single major industrial grouping and that directly emits or has the potential to emit greater than 100 tpy of any criteria air pollutant, 10 tpy of a single HAP, or 25 tpy of all HAP combined.

82. EPA approved Ohio's Title V operating program effective October 1, 1995, and revisions on December 22, 2003. See 60 Fed. Reg. 42045, and 68 Fed. Reg. 65401. Ohio's Title V operating permit program regulations are codified at Ohio Rule 3745-77 and are federally enforceable pursuant to Section 113(a)(3) of the CAA, 42 U.S.C. § 7413(a)(3).

Finding of Facts

83. MilliporeSigma owns and operates a batch specialty chemical manufacturing facility at 4353 East 49th Street, Cleveland, Ohio (Facility).

84. At its Facility, MilliporeSigma manufactures various biological buffers and amino acids using a variety of reactions that use HAPs, such as methanol and hydrochloric acid. The Facility has NAICS code 325199.

85. MilliporeSigma emits methanol and other HAPs in a combined quantity of over 25 tpy, and is thus a major source of HAPs, as defined in Section 112(a) of the CAA, 42 U.S.C. § 7412(a).

86. On April 30, 2012, MilliporeSigma submitted to Ohio Environmental Protection Agency (OEPA), Cleveland Department of Public Health, Division of Air Quality, a voluntary disclosure form stating that Facility's potential to emit was revised from synthetic minor to major source of HAPs, and as a result the Facility became subject to all the requirements of the Subpart FFFF.

87. On May 17, 2013, MilliporeSigma submitted to the Cleveland Department of Public Health (with copies directed to OEPA and EPA) its Subpart FFFF Initial Notification, pursuant to 40 C.F.R. § 63.2515(b).

88. On February 9, 2015, MilliporeSigma submitted to OEPA and EPA the Notification of Compliance Status (NOCS) report, pursuant to 40 C.F.R. § 63.2520(d).

89. On July 6, 2016, the OEPA issued to MilliporeSigma an operating permit effective July 27, 2016, permit number P0112455 (Title V permit) for its Facility.

90. From August 14, 2017 through August 16, 2017, EPA conducted an unannounced CAA investigation of the Facility for compliance with Subpart FFFF (2017 Inspection)

91. According to the MilliporeSigma's 2015 NOCS report, the batch manufacturing process includes multiple steps and equipment units, generally including heating raw materials and solvents (primarily methanol, isopropanol, and water), in reactors, followed by cooling in crystallizers/chillers, separation of solid product in centrifuges, and drying in tumble dryers. The facility manufactures multiple products and not all products required all these steps or equipment units, and some steps may be used more than once. Different equipment units are connected (or disconnected) as necessary for a specific product.

92. According to the MilliporeSigma's 2015 NOCS report, for purposes of compliance with Subpart FFFF, each configuration of equipment necessary to produce a batch-manufactured product is an MCPU, as defined at 40 C.F.R. § 63.2435(b). MilliporeSigma has chosen to comply with Subpart UU for leak detection and repair (LDAR).

93. According to the MilliporeSigma's 2015 NOCS report, the Facility contains both Group 1 and Group 2 batch process vents and Group 1 wastewater streams, but has only Group 2 storage or wastewater tanks. Organic HAP emissions from the Group 1 process vents are captured by a closed-vent system and routed to what the NOCS report describes as an "enclosed ground flare" or as a "flare" and the halogen HAP emissions from MCPU equipment amounting to more than 1,000 lb/year are captured by a closed-vent system and routed to a caustic soda scrubber. The Group 1 wastewater streams are sent to a waste collection tank (hazardous waste tank) for offsite disposal as hazardous waste.

94. According to MilliporeSigma's 2015 NOCS report, the enclosed ground flare "is monitored using a 'fire eye' ultraviolet (UV) flame detector to continuously monitor that the pilot flame is present as required by 40 C.F.R. 63.987(c)." The NOCS report does not describe any other monitoring used for the "enclosed ground flare," and the provisions of 40 C.F.R. § 63.987 are required for only for flares and are not required for other combustion-based control devices like "incinerators," as defined in 40 C.F.R. § 63.981.

95. The Facility's operations result in multiple vent emission streams, including vent streams with organic HAP but no hydrogen halide or halogen HAP; vent streams with hydrogen halide or halogen HAP but no organic HAP; and vent streams with both organic HAP and hydrogen halide or halogen HAP.

96. According to the MilliporeSigma's 2015 NOCS report, a design evaluation (engineering assessment) was completed for the scrubber in April 2014, in accordance with Subpart FFFF, at 40 C.F.R. § 63.2465(c)(1), and 40 C.F.R. § 63.1257(a)(1). The following operating parameters limits were established during the design evaluation to achieve a 99% control efficiency required by the MON: scrubber liquid effluent pH of greater than or equal (\geq) to 8.0; scrubber liquid influent flow (recirculation rate) of \geq 90 gallons per minute (gpm); and scrubber gas influent flow of lower than or equal to 3,000 standard cubic feet per minute. MilliporeSigma monitors pH of the scrubber effluent using a temperature compensating pH probe, scrubber recirculation rate using an in line flow meter, and scrubber gas influent flow using the design blower capacity and total static pressure drop of 5.2 inches of water column.

97. As described in a Compliance Test Report dated February 25, 2014, the Facility arranged for emissions testing of the enclosed ground flare (called the "Enclosed Flare" in the report) on February 12-13, 2014, for the purpose of demonstrating "compliance with the Ohio Environmental Protection Agency Permit No. P0114439 and with 40 C.F.R. Part 63, Subparts SS and FFFF." The compliance test report provided information on emissions from the enclosed ground flare, the enclosed ground flare's destruction efficiency for hazardous organic compounds, and visual emissions. The test for destruction efficiency consisted of measuring inlet and outlet emissions from the enclosed flare over three one-hour long test runs. Table 2.2 reported an average destruction efficiency of 99.54% at a temperature of 509° F averaged over three runs. The temperature 509° F thus potentially represents – provided the applicable requirements for performance tests were met - that temperature at which the destruction efficiency of the enclosed ground flare might comply with the requirements of Subpart FFFF. Nevertheless, this result was not characterized in the Compliance Test Report as an operating limit for the operations of the enclosed ground flare, nor was it reported in the NOCS report as an operating limit.

98. During the 2017 Inspection, EPA observed that the control device described in the NOCS as the "enclosed ground flare" had an enclosure around the flame.

99. During the 2017 Inspection, EPA recorded a forward-looking infrared (FLIR) Video 3 (MOV 1864) of the control device showing un-combusted hydrocarbons leaving the stack.

100. During the 2017 Inspection, EPA found the level indicator on top of the methanol tank (Tank #1 of 9,960 gallons of nominal capacity), leaking on August 14, 2017 (FLIR Video 1; MOV 1862) and August 15, 2017 (FLIR Video 4; MOV 1865). On August 15, 2017, MilliporeSigma's LDAR consultant, Emission Monitoring Service, Inc. (EMSI), confirmed the leak in the presence of the inspectors by recording a 20,000 ppmv VOC reading at the level indicator on top of the Tank #1.

101. During the 2017 Inspection, EPA found the pressure gauge on top of the hazardous waste tank leaking on August 15, 2017 (FLIR Video #5; MOV 1866). On August 15, 2017, EMSI confirmed the leak in the presence of the inspectors by recording a 29,000 ppmv VOC reading at the pressure gauge on top of the hazardous waste tank.

102. During the 2017 Inspection, MilliporeSigma informed EPA staff that the Facility had no additional components added to its MPCUs since the Facility became subject to Subpart FFFF i.e., since April 30, 2015.

103. On August 15, 2017, MilliporeSigma provided EPA with the LDAR monitoring data from its LeakDAS database.

104. From the review of the MilliporeSigma's LDAR database, EPA discovered that the several valves were not always part of the LDAR database and were not monitored monthly for varying numbers of monthly monitoring periods of time as summarized below:

Number of Valves	Date Added to LDAR Database	Monthly Monitoring Periods Missed
7	August 24, 2015	3
12	December 16, 2015	7
3	February 9, 2016	9
3	April 1, 2016	11
2	April 15, 2016	11
2	May 10, 2016	12
8	August 3, 2016	15
9	October 18, 2016	17
4	January 3, 2017	20
26	April 13, 2017	23
2	July 26, 2017	27
3	August 7, 2017	27

105. During the 2017 Inspection, EPA found one missing identification tag for one of the connectors at Tank #1, that was not identified in any other way.

106. From a review of the methanol tanks (Tank #1 and #2), and the hazardous waste tank's process and instrumentation diagrams, and also considering the Facility's historical leaking measured emissions, EPA determined that several connectors on top of the tanks come in contact with regulated materials. From the review of the MilliporeSigma's LDAR database, EPA discovered that these connectors are not part of the Facility's LDAR program database, and thus have not been monitored for leaks.

107. On February 13, 2018, MilliporeSigma submitted to EPA via e-mail, in response to an EPA e-mail dated February 13, 2018, a manufacturer specification and cost data about the control device described in the NOCS report as an enclosed ground flare. The manufacturer specification recommended a minimum temperature of 400 degrees Fahrenheit to achieve a 95% VOC destruction efficiency. The manufacturer specification describes the position of the pilot light inside of the flare to be enclosed at the bottom of the stack, the assist air blower to be at the bottom of the stack with adjustable dampers to control air flow, and the assist gas control valve and quench air dampers modulate independently to maintain the combustor temperature.

108. In its semi-annual MON reports for the Facility dated August 28, 2015, February 11, 2016, August 31, 2016, February 28, 2017, August 31, 2017, and February 28, 2018, covering the reporting period of February 9, 2015, through December 31, 2017, MilliporeSigma reported as deviations that the Facility failed to maintain scrubber manufacturer recommended make-up flow rate for a total of 9 times during the reporting period and for a duration of approximately 170 hours, as follows:

Date	Duration (Hours)	Corrective Actions Taken
1/5/2015	24	The Facility attempted to identify a new water source to provide uninterrupted flow rates for make-up flow. A new suitable location could not be determined, so in September, a consultant was contracted to document all of our water supply piping. Currently, it is unknown where the new supply line will originate. In addition, there were no deviations regarding make-up flow rate in the fourth quarter of 2015. We expect to identify the location of a replacement source by March 13, 2016. Once the scope of work is defined, we will install a new water line.
1/15/2015	24	Same as above.
1/30/2015	24	Same as above.
3/25/2015 to 3/27/2015	72	Same as above.
3/31/2015	24	Same as above.
6/4/2015	0.5	Same as above.
6/23/2015	0.2	Same as above.
Total	170	

109. In its semi-annual MON reports for the Facility dated August 28, 2015, February 11, 2016, August 31, 2016, February 28, 2017, August 31, 2017, and February 28, 2018, covering the reporting period of February 9, 2015, through December 31, 2017, MilliporeSigma reported as deviations that the Facility failed to maintain scrubber manufacturer recommended recirculation flow rate for a total of 23 times during the reporting period and for a duration of approximately 240 hours, as follows:

Date	Duration (Hours)	Corrective Actions Taken
4/9/2015	1	The recirculation flow rate was outside (low) the manufacturers recommendations. Our investigation was unable to pinpoint the specific cause of the low recirculation flow rates. We have consulted with the manufacturer, and on 01/19/16 the recirculation pump was replaced at their recommendation.
4/10/2015	1	Same as above.
4/13/2015	1	Same as above.
4/16/2015	1	Same as above.
4/18/2015	1	Same as above.
4/20/2015	2	Same as above.

4/21/2015	1	Same as above.
4/23/2015	1	Same as above.
4/24/2015	1	Same as above.
4/26/2015	1	Same as above.
4/28/2015	1	Same as above.
5/1/2015	2	Same as above.
6/4/2015	0.5	Same as above.
6/22/2015 to 6/23/2015	48	The recirculation flow rate of tower 1 was outside (low) of the manufacturers recommendations. Engineering consulted the scrubber manufacturer and tuned the pump settings accordingly in July.
6/22/2015 to 6/25/2015	96	Same as above; The recirculation flow rate of tower 2 was outside (low) of the manufacturers recommendations. Engineering consulted the scrubber manufacturer and tuned the pump settings accordingly in July.
6/29/2015	24	Same as above;
6/29/2015 To 6/30/2015	48	Same as above;
7/20/2015	0.8	Same as above;
7/21/2015	1	Same as above.
7/22/2015	6.8	Same as above.
Total	240	

110. In its semi-annual MON reports for the Facility dated August 28, 2015, February 11, 2016, August 31, 2016, February 28, 2017, August 31, 2017, and February 28, 2018, covering the reporting period of February 9, 2015, through December 31, 2017, MilliporeSigma reported as deviations that the Facility failed to maintain scrubber manufacturer recommended effluent pH for a total of 6 times during the reporting period and for a duration of approximately 73 hours, as follows:

Date	Duration (Hours)	Corrective Actions Taken
1/26/2015 To 1/27/2015	48	The pH probes were replaced in August 2015 and will be replaced on an annual basis. In addition, the instructions on how to calibrate the pH probe were revised in September 2015. It is thought that equipment and calibration issues caused the fluctuations observed, which have not been identified since the activities were completed. All maintenance personnel were retrained on the scrubber log documentation process on 06/05/15.
1/29/2015	24	Same as above.
7/20/2015	0.3	Same as above.
7/21/2015	0.3	Same as above.
4/24/2016	6	The scrubber had a pH reading that was below the manufacturer's recommendation, thought to be due to a PM, and was returned to production. When it was found after production was started, it was investigated further. It was found that the sump overflow pH was

		within the manufacturer's recommendations. The pH from the sump overflow was checked once an hour until production venting to the scrubber completed. No new processes venting to the scrubber were started. On 04/26/16, the pH probe was found to be cracked, and the pH probe was replaced and calibrated. All Maintenance personnel were retrained that all parameters of the scrubber must be in compliance prior to returning the scrubber for production use.
Total	73	

111. In its semi-annual MON reports for the facility dated August 28, 2015, February 11, 2016, August 31, 2016, February 28, 2017, August 31, 2017, and February 28, 2018, covering the reporting period of February 9, 2015, through December 31, 2017, MilliporeSigma reported as deviations that the Facility failed to record scrubber's flow and pH monitoring for a total of 74 times during the reporting period and for a duration of approximately 1,775 hours, as follows:

Date	Duration (Hours)	Corrective Actions Taken
02/10/2015 to 02/15/2015	96	A chart recorder was utilized to continuously record the pH, but not the flow rate. The error was discovered, and the flow rate was continuously recorded when the recordkeeping was transferred to an electronic monitoring device on 03/19/15. In the future, all compliance changes will be routed through the management of change (MOC) process.
02/24/2015 to 03/19/2015	576	Same as above.
03/19 /2015 to 03/31/2015	301	Continuous flow and pH monitoring was completed by an electronic monitoring device; however, the documentation could not be retrieved. The programming of the electronic monitoring device was changed on 05/04/15 to record data as required.
04/01/2015 to 04/06/2015	131	Same as above.
04/06/2015 To 05/04/2015	671	Continuous flow and pH monitoring were completed by an electronic monitoring device; however, the data was corrupt, and only hourly reports were available. The reports contained the hourly average, minimum, and maximum values. Daily checks and the hourly report identified flow rates and pH within the manufacturers recommendations (except where noted below). The programming of the electronic monitoring device was changed on 05/04/15 to record data as required.
Total	1,775	

Alleged Violations

112. As a result of improperly classifying the “enclosed ground flare” as a flare, rather than an enclosed combustion device, as indicated in paragraphs 94, 98, and 107, for purposes of 40 C.F.R. Part 63, Subpart FFFF, and 40 C.F.R. Part 63, Subpart SS, MilliporeSigma failed to satisfy the requirements in Subpart FFFF and Subpart SS for control devices that are not flares but that are used to reduce organic HAP emissions from batch process vents, in violation of Subpart A at 40 C.F.R. § 63.4, Subpart FFFF at 40 C.F.R. § 63.2460(a), and the requirements summarized in paragraphs 17 and 19 through 22 above, and Subpart G at 40 C.F.R. § 63.139(c)(1), among others, allowing the release of uncontrolled organic HAP emissions.

113. MilliporeSigma failed to capture and control emissions from Tank #1 and hazardous waste tank, as indicated in paragraphs 100 through 101, in violation of the Subpart A at 40 C.F.R. § 63.4, Subpart FFFF at 40 C.F.R. § 63.2460(a) and Subpart SS at 40 C.F.R. § 63.983(a).

114. MilliporeSigma failed to timely identify numerous valves that are in organic HAP service, as referenced in paragraphs 102, 103, and 104, in violation of the Subpart A at 40 C.F.R. § 63.4, Subpart FFFF at 40 C.F.R. § 63.2480(a), and Subpart UU at 40 C.F.R. § 63.1022(a).

115. From August 24, 2015 through at least August 7, 2017, MilliporeSigma failed to perform monthly Method 21 monitoring for valves listed in Paragraph 104, in violation of the Subpart A at 40 C.F.R. § 63.4, Subpart FFFF at 40 C.F.R. § 63.2480(a), and Subpart UU at 40 C.F.R. § 63.1025(b)(3)(i) and 63.1023(b)(1).

116. MilliporeSigma failed to identify a number of connectors, as referenced in paragraphs 105 and 106, in violation of the Subpart A at 40 C.F.R. § 63.4, Subpart FFFF at 40 C.F.R. § 63.2480(a), and Subpart UU at 40 C.F.R. § 63.1022(a).

117. From not later than April 30, 2015 to present, MilliporeSigma failed to perform annual Method 21 monitoring for connectors as indicated in Paragraph 104, in violation of the Subpart A at 40 C.F.R. § 63.4, Subpart FFFF at 40 C.F.R. § 63.2480(a), and Subpart UU at 40 C.F.R. § 63.1027(b).

118. MilliporeSigma failed to meet the inspection and monitoring requirements for a closed vent system for the Tank #1 and hazardous waste tank, as indicated in paragraphs 100, 101, and 101, in violation of the Subpart A at 40 C.F.R. § 63.4, Subpart FFFF at 40 C.F.R. § 63.2450(e)(1), and Subpart SS at 40 C.F.R. § 63.982(c), 63.983(a), and 63.983(c)(1)(i).

119. MilliporeSigma failed to operate the scrubber in accordance with operating parameters established through the design evaluation, as indicated in paragraphs 96, and 108 through 111, in violation of the Subpart A at 40 C.F.R. § 63.4, and Subpart FFFF at 40 C.F.R. §§ 63.2450(e)(3) and 63.2465, and Subpart SS at 40 C.F.R. § 63.994.

120. MilliporeSigma failed to operate and maintain the scrubber at its Facility in a manner consistent with safety and good air pollution control practices for minimizing emissions,

as indicated in paragraphs 96 and 108 through 111, in violation of Subpart FFFF at 40 C.F.R. § 63.2540 and the Subpart A at 40 C.F.R. § 63.6(e)(1).

121. MilliporeSigma failed to operate and maintain the enclosed combustion device at its Facility in a manner consistent with safety and good air pollution control practices for minimizing emissions, as indicated in paragraphs 94 and 107, in violation of Subpart FFFF at 40 C.F.R. § 63.2540 and Subpart A at 40 C.F.R. § 63.6(e)(1).

122. MilliporeSigma failed to maintain records of the scrubber's effluent pH and influent flow rate to demonstrate compliance with Subpart SS, as indicated in Paragraph 111, in violation of the Subpart SS at 40 C.F.R. § 63.982(c), 40 C.F.R. § 63.994(c)(1), 40 C.F.R. § 63.996, and 40 C.F.R. § 63.998.

Environmental Impact of Violations


123. These violations have caused excess emissions of VOCs and HAPs.

124. VOCs are precursors in the formation of atmospheric and ground-level ozone, a photochemical oxidant associated with a number of detrimental health effects, environmental, and ecological effects. Breathing ozone contributes to a variety of health problems including chest pain, coughing, throat irritation, and congestion. It can worsen bronchitis, emphysema, and asthma. Ground-level ozone also can reduce lung function and inflame lung tissue. Repeated exposure may permanently scar lung tissue.

125. HAP emissions increase the amount of pollutants that are known or suspected to cause cancer or other serious health effects, such as reproductive effects or birth defects and/or adverse environmental effects.

6/29/18

Date



Edward Nam

Director

Air and Radiation Division

CERTIFICATE OF MAILING

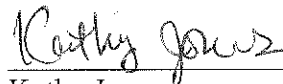
I certify that I sent a Finding of Violation, No. EPA-5-18-OH-08, by Certified Mail, Return Receipt Requested, to:

Michael Shuler, Environmental Specialist
MilliporeSigma
4353 East 49th Street
Cleveland, Ohio 44125

I also certify that I sent copies of the Finding of Violation by first-class mail to:

Bob Hodanbosi, Chief
Division of Air Pollution Control
Ohio Environmental Protection Agency
bob.hodanbosi@epa.ohio.gov

On the 29th day of June 2018



Kathy Jones
Program Technician
AECAB, PAS

CERTIFIED MAIL RECEIPT NUMBER: 7017 1070 0000 1030 0010

